K010222

MAR 21 2001

Ohmeda Medical Giraffe™ Incubator
510(k) Summary

Submitter Information

Alberto F. Profumo, RAC
8880 Gorman Road
Laurel, MD 21046-1801
Tel. (410) 888-5204
Summary prepared on JAN 19 2001

Device Name(s)

Classification Name:
- Neonatal Incubator

Common Name:
- Incubator

Proprietary Name:
- Ohmeda Medical Giraffe™ Incubator

Predicate Device Information

The Giraffe Incubator is substantially equivalent to the Ohmeda Medical – OmniBed

Product Description

The Giraffe Incubator is an infant bed which provides thermal support for infants who are unable to provide for their own heat requirements.

The bed functions as an incubator, maintaining the infant's temperature by circulating heated air within the enclosed bed compartment. The operator may select either the air or skin temperature control method. Depending on the control method selected, heat is regulated based on either the air temperature or the infant's skin temperature compared to the operator selected control temperature. Physical access to the patient is obtained through the side portholes or by opening one of the side doors. The humidity and oxygen may also be increased. If an optional scale is provided the weight of the patient will be displayed along with incubator parameters.

Indications for Use

The Giraffe Incubator is an infant incubator. Incubators provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Incubators provide an enclosed temperature controlled environment.

Assessment of Technological Characteristics

The technological characteristics of the Giraffe Incubator are similar to those of predicate devices and do not raise new safety or effectiveness issues.

Performance Data

Since care of newborns in incubators is a well established clinical practice, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product was subject to extensive bench testing, the software was validated, and, to the best of Ohmeda Medical's knowledge, the requirements of 21 CFR 820, Subpart C – Design Controls – were satisfied.

Sterilization Information

The Giraffe™ Incubator is not intended to be sterilized. Cleaning and disinfecting instructions can be found in the Operations and Maintenance Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2001

Ms. Alberto F. Profumo
Director of Product Assurance
Ohmeda Medical
8880 Gorman Road
Laurel, Maryland 20723

Re: K010222
Trade Name: Giraffe™ Incubator
Regulatory Class: II
Product Code: FMZ
Dated: January 19, 2001
Received: January 24, 2001

Dear Mr. Profumo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Giraffe ™ Incubator

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010222

Prescription Use ✓ OR Over- The Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)